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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,634	12/05/2003	Peter M. Bonutti	2500 DIV 2 CON 2 DIV 3 CO	1118
7590 03/13/2008 Kimberly V. Perry, Esq. U.S. Surgical, A Division of Tyco Healthcare Group, LP 150 Glover Avenue Norwalk, CT 06856			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 03/13/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/729,634	Applicant(s) BONUTTI, PETER M.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9,13 and 16-33 is/are pending in the application.
- 4a) Of the above claim(s) 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-9, 13 and 16-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 1, 4-9, 13, and 16-32 in the reply filed on December 17, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claim 33 is directed to an invention that is independent or distinct from the invention elected for the following reasons: It is directed to a retractor including, inter alia, a plurality of inflatable filaments.

Since applicant has received an action on the merits for the originally presented invention (restriction requirement of 11/14/07), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 33 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

2. Claims 27-29 are objected to because of informalities, which can be corrected as follows: In claim 27, line 1; claim 28, line 1; and claim 29, line 3: Insert "--member--" after "sleeve." Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect base claim 5, “the inflatable bladder” lacks antecedent basis.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 7, 18, 20, and 24-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Arthur (972,983). Arthur discloses, at least in figures I-VIII and in lines 31-98; a retractor including a shaft (D) extending at least partially through a cannula (A); a plurality of filaments (C) extending from the cannula, the plurality of filaments being repositionable from a first condition to a second condition; a sleeve (E) or sleeve member coaxially disposed and movable with respect to the cannula, the sleeve being axially movable between a first position and a second position; and a positioner (B or d, d3, and d4 combined) disposed at a distal end of the shaft; where the shaft is rigid, where the sleeve is formed of a rigid (solid) material, where the plurality of filaments is pivotally disposed at a distal end of the cannula or is pivotally connected to the shaft (via B), where the sleeve member is coaxially disposed with respect to the shaft and being movably supported thereon such that the sleeve is repositionable amongst a plurality of positions including at least a first position and a second position (e.g., from

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compression, expansion and/or translation), where the sleeve member (E) is axially movable (e.g., from compression, expansion and/or translation) with respect to the shaft between the first and second positions, where the sleeve member is at least partially disposed about the plurality of filaments in the first position, where the sleeve member is disposed proximally of the plurality of filaments in the second position, where the sleeve member allows the plurality of filaments to transition from a first state to at least one subsequent state when the sleeve member is in a proximalmost position, where the sleeve member maintains the plurality of filaments in a first state when the sleeve member is in a distalmost position, and where the plurality of filaments is parallel in a first state or condition (i.e., the state or condition between the states or conditions as shown in figures VII and VIII) and extends radially outward in at least one subsequent state or second condition (e.g., see fig. II or VIII).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 1, 4-6, 8, 9, 13, 16, 17, 19, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz (4,733,665) in view of Horzewski et al. (4,932,959). Palmaz discloses the invention substantially as claimed. Palmaz discloses, at least in figures 1A, 1B, 3, and 4 and in col. 5, line 58 to col. 6, line 36 and col. 7, line 29 to col. 8, line 24; a retractor including a retractor including a plurality of filaments (75, 76) extending from a cannula (89), the plurality of filaments being repositionable from a first condition (a first diameter or sheathed condition) to a second condition (an enlarged diameter or unsheathed condition) ; a sleeve (83) coaxially disposed and movable with respect to the cannula, the sleeve being axially movable between a first position and a second position; and a positioner (88), where the positioner is an inflatable bladder, where the cannula defines a passage, where the plurality of filaments is disposed about the (proximal) periphery of the positioner, where the positioner does not stretch when fully inflated, where the plurality of filaments is formed of an at least semi-rigid material (e.g., stainless steel), where the sleeve is formed of a flexible material (e.g., TEFLON), where inflation of the positioner repositions the plurality of filaments from the first condition to the second condition, where the distal positioning of the sleeve relative to the cannula repositions the plurality of filaments from the second condition (unsheathed, with respect to claim 22) to the first position (sheathed), and where proximal positioning of the sleeve relative to the cannula maintains the plurality of filaments in the first condition (sheathed, with respect to claim 23). However, Palmaz does not disclose that the retractor includes a flexible shaft

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extending at least partially through the cannula, although the sleeve includes a lumen that can accommodate a shaft. Horzewski et al. teach, at least in figures 1 and 2 and in col. 3, lines 1-5 and 26-35; a flexible shaft (16) extending through a lumen of a balloon catheter similar to the sleeve and positioner of Palmaz. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Horzewski et al. , to include a flexible shaft with Palmaz's device. Such a shaft would allow the guidance and positioning of Palmaz's device through the narrow confines of a tissue pathway and/or surgical site, and such a shaft would allow mechanical support (stiffening) for at least the sleeve and positioner of the device as it is inserted into a patient's body.

Palmaz also does not specifically disclose that the inflation bladder operates at inflation pressures from 10 mmHg to 1000 mmHG or from 100 mmHg to 1000 mmHg. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the inflation pressures as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (of inflation pressure) involves only routine skill in the art.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

March 19, 2008